Docket No.: 17469/004001
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
BuSang Liu et al.

Application No.: 10/811,420 | Confirmation No.: 2642

Filed: March 26, 2004 | Art Unit: 1614

For: TOPICAL COMPOSITION FOR TRANSDERMAL ADMINISTRATION | Examiner: Zohreh VAKILI

MS: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF UNDER 37 C.F.R. § 41.37

Pursuant to 37 CFR § 41.37, please consider the following Appellant's Brief in the referenced application currently before the Board of Patent Appeals and Interferences.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statute

Other Authorities

I. Real Party of Interest

The real party of interest for the referenced application is Lotus Pharmaceutical Co., Ltd. An Assignment transferring all interest in the referenced application from inventors to Lotus Pharmaceutical Co., Ltd. was filed with the USPTO on March 26, 2004. The Assignment is recorded at Reel 015163, Frame 0322.

II. Related Appeals and Interferences

To the best of the knowledge of the Appellants and Appellants' legal representative, there are no other appeals or interferences that will directly affect, be affected by, or have a bearing on the decision of the Board of Patent Appeals and Interferences ("the Board") in this appeal.

III. Status of Claims

U.S. Application Serial No. 10/811,420 ("the '420 Application") was filed as a national stage application on March 26, 2004, claiming benefits of PCT Application No. PCT/CN2003/000358, filed in China on May 16, 2003, and Chinese Patent Application Serial No., 03136028.9,[1] filed on May 16, 2003. As filed, the '420 Application included claims 1-9.

In the first Office Action on the merits dated October 4, 2006, claim 8 was rejected under 35 U.S.C. 112 and 35 U.S.C. 112 101. In addition, claims 1-9 were rejected under 35 U.S.C. 103(a) as being obvious over Murad (U.S. Patent No. 6,630,163), in view of Murad (U.S. Patent No. 5,962,517), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852). Claims 1-9

[1] Claim to this Chinese Priority Application was made in a Preliminary Amendment filed on July 13, 2004. However, the record in the Public Pair shows only the PCT application as the priority application.

were also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 15-17 of serial number 11/446,051.

A response to the first Office Action was filed on February 2, 2007, in which claims 1 and 5-8 were amended to clarify the invention recited. A terminal disclaimer was also filed to overcome the obviousness-type double patenting rejection.

In the final Office Action dated October 5, 2007, the Examiner maintained all previous rejections under 35 U.S.C. 103(a).

An early reply to the final Office Action was filed on December 4, 2007. The Final Rejection was sustained in an Advisory Action dated January 15, 2008.

A Request for Continued Examination (RCE) was filed on February 15, 2008, in which claims 1 and 5-7 were amended.

A non-final Office Action was mailed on April 2, 2008, in which claims 1-9 were rejected under 35 U.S.C. 112, second paragraph, and under 35 U.S.C. 103(a) for the same reasons set forth in the previous office actions.

A response was filed on July 1, 2008, in which claims 1-2 and 5-7 were amended. A final Office Action was mailed on October 30, 2008, in which claims 1-9 were rejected under 35 U.S.C. 112 as including new matter, and under 35 U.S.C. 103(a) for the same reasons set forth in the previous office actions.

An early response was filed on December 30, 2008, in which claims 1 and 5-7 were amended. In response, the Examiner issued an Advisory Action on February 5, 2009, in which the

Examiner indicated that for purpose of appeal, the claim amendments would be entered. Thus, the claims as amended are presented in the Appendix.

A petition for pre-appeal brief conference was filed on March 5, 2009. In a Panel Decision from Pre-Appeal Brief Review mailed on April 3, 2009, the rejections of claims 1-9 were maintained.

Therefore, all pending claims 1-9 stand finally rejected for reasons set out in the Office Action dated October 30, 2008 ("Final Rejection").

Claims 1-9 are on appeal.

IV. Status of Amendments

The claim amendments presented in the Response to the Final Office Action were entered for this Appeal, as indicated by the Advisory Action of February 5, 2009. The claims as emended are shown in Appendix A.

V. Summary of Claimed Subject Matter

Appellant proffers the following summary of the claimed subject matter, identifying exemplary support in the as-filed specification and drawings. While examples of supporting disclosure are presented, it should be understood that additional examples and/or embodiments may also be disclosed within the specification and drawings as well.

Independent claim 1

Independent claim 1 recites a topical composition for transdermal administration, comprising: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, and 2 - 90% w/w vitamin E, wherein the composition is substantially free of vitamin A or vitamin A acid.

As noted in the specification, vitamin A acid-containing products may make the skin sensitive to the light, and overuse of products containing vitamin A acids may cause side effects, such as dry skin, red swelling, itching and dermatitis. (p. 4, lines 10-13, ¶ [0009]). Thus, one of the objectives of the invention is to provide a topical composition that is free of vitamin A acid and may be used for skin care. (p. 4, lines 20-22, ¶ [0011]). Accordingly, a composition of the invention comprises carotene instead of vitamin A or vitamin A acid, e.g., vitamin C 1-45% w/w, vitamin B complex 1-5% w/w, carotene 1-3% w/w, and vitamin E 2-90% w/w. (p. 4, lines 23-25, ¶ [0012]).

Specifically, independent claim 1 requires, *inter alia*, "wherein the composition is substantially free of vitamin A or vitamin A acid."

By virtue of their dependency from independent claim 1, dependent claims 2-4, 8, and 9 require the same limitation – i.e., "substantially free of vitamin A or vitamin A acid."

Independent claim 5

Independent claim 5 recites a topical composition for transdermal administration, said composition is for use in manufacturing a medication for treating acne, comedo or zit, (p. 8, lines 3-4, ¶ [0028]), wherein the composition comprises: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, 2 - 90% w/w vitamin E, 0.1 - 2% w/w fragrance, 1 - 5%

w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water, wherein the composition is substantially free of vitamin A or vitamin A acid.

Like claim 1, independent claim 5 requires, *inter alia*, "wherein the composition is substantially free of vitamin A or vitamin A acid."

Independent claim 6

Independent claim 6 recites a topical composition for transdermal administration, said composition is for skin-care (p. 14, lines 10-13, ¶ [0049]), wherein the composition comprises: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, 2 - 90% w/w vitamin E, 0.1 - 2% w/w fragrance, 1 - 5% w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water, wherein the composition is substantially free of vitamin A or vitamin A acid.

Like claim 1, independent claim 6 requires, *inter alia*, "wherein the composition is substantially free of vitamin A or vitamin A acid."

Independent claim 7

Independent claim 7 recites a topical composition for transdermal administration, said composition has an antioxidant property (p. 5, lines 10-11, ¶ [0015]), wherein the composition comprises: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, 2 - 90% w/w vitamin E, 0.1 - 2% w/w fragrance, 1 - 5% w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water, wherein the composition is substantially free of vitamin A or vitamin A acid.

Like claim 1, independent claim 7 requires, *inter alia*, "wherein the composition is substantially free of vitamin A or vitamin A acid."

VI. Grounds of Rejection to be Reviewed on Appeal

The present Appeal addresses the following sole ground of rejection:[2]

- Whether claims 1-9 are obvious, under 35 U.S.C. § 103(a) over Murad (U.S. Patent No. 6,630,163), in view of Murad (U.S. Patent No. 5,962,517), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852).

VII. Argument

A. Claims 1-9 are not obvious, under 35 U.S.C. § 103(a), over Murad (U.S. Patent No. 6,630,163), in view of Murad (U.S. Patent No. 5,962,517), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852).

In this appeal, the Appellant asserts, for purpose of the 35 U.S.C. § 103(a) rejection, that claims 1-9 stand or fall together.

Claims 1-9 are rejected as being obvious, under 35 U.S.C. § 103(a), over Murad (U.S. Patent No. 6,630,163; hereinafter "Murad '163"), in view of Murad (U.S. Patent No. 5,962,517; hereinafter "Murad '517"), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852).

The Examiner asserts that "if a composition contains carotene [sic] this composition is not substantially free of Vitamin A or its derivatives, because carotene is a precursor of Vitamin A, [sic] therefore, the composition is not substantially free of Vitamin A or its derivatives." (final Office Action, p. 8, ll. 7-10; see also, Advisory Action, p.2, lines 10-11).

[2] Although the Advisory Action did not specifically address the issue of the rejection under 35 U.S.C. 112, Applicant believes this rejection is overcome since the claim amendments are entered for the purpose of this appeal. The claim amendments put back "substantially free of vitamin A and vitamin A acid," which was previously presented and was not rejected.

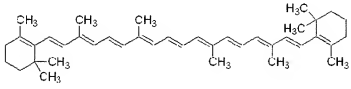
Applicant believes the assertion that because carotene is a precursor of vitamin A, a composition containing carotene is not substantially free of vitamin A or vitamin A derivatives can be sustained only if: (1) carotene is vitamin A or a vitamin A derivative, or (2) carotene is readily converted into vitamin A or a vitamin A derivative such that there is no difference between them.

First, claim 1 recites "substantially free of vitamin A or vitamin A acid," not "substantially free of vitamin A or vitamin A derivatives." Carotene, vitamin A, and vitamin A acid are distinct chemical entities (see the structures shown below). Thus, carotene cannot be vitamin A or vitamin A acid. The fact that the Examiner recognizes that carotene is a precursor of vitamin A indicates that the Examiner also agrees that carotene is not the same as vitamin A because a precursor cannot be the same entity as the product.

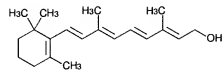
Accordingly, Applicant believes the only ground that can support the Examiner's position is that carotene is readily converted into vitamin A or vitamin A acid in such a manner that there is no distinction between them. However, this is not supported by any scientific facts.

(A) Carotene can be converted into vitamin A only via multiple step reactions.

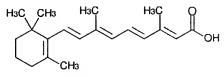
As noted above, carotene and vitamin A[3] are different chemical entities. (*see* the chemical structures shown below).



β-carotene



vitamin A



vitamin A acid

[3] Vitamin A can be retinol (an alcohol, as shown in the structure) or its aldehyde form, retinal. Most vitamin A is in the alcohol form, i.e., retinol, which may exists as an ester with an acid.

Although carotene is a precursor of vitamin A, conversion of carotene into vitamin A involves slow enzymatic steps *in vivo*. Thus, carotene is not readily converted into vitamin A in such a manner that the two can be considered the same. For example, a report by the scientists at the U.S. Department of Agriculture (USDA) (Agriculture Research, March 2001, p. 12-13, a copy of which was submitted with the Reply filed on December 4, 2007) shows that in some individuals, the conversion from carotene to vitamin A in human body can take more than 3 days and the efficiency can be extremely low (8%). (p. 12, right column, lines 14-16). Even in subjects who have more efficient enzymes, the process took 12 hours to achieve 30% conversion. (p. 12, right column, lines 10-13). Note that carotene was taken orally by the individuals in these experiments. In contrast, a composition of the invention is to be used topically on the skin. It is doubtful that all these enzymes are available on the skin. In any event, the above-described results clearly show that carotene is not readily converted into vitamin A in such a manner that they can be considered the same entity.

Furthermore, the patentability of a composition should be judged based on the combination of its components as claimed, not how one of its components could have been converted.

For reasons set forth above, Applicant respectfully summits that carotene is not vitamin A or vitamin A acid, nor is it readily converted into vitamin A in such a manner that there is no distinction between them. Accordingly, contrary to the Examiner's assertion, a composition containing carotene can be substantially free of vitamin A or vitamin A acid, even though carotene is a precursor of vitamin A.

(B) A combination of Murad '517, Murad '163, and Gildenburg '852 fails to teach or suggest all limitations of the claims in the present application.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

Applicant respectfully submits that a combination of Murad '517, Murad '163, and Gildenburg fails to teach or suggest at least one limitation of the claims of the invention, i.e., "wherein the composition is substantially free of vitamin A or vitamin A acid." In fact, the Examiner never specifically asserted that the combined teaching of these references discloses this particular limitation of the independent claims 1 and 5-7 of the present application. The Examiner disregarded this limitation during the prosecution because the Examiner does not believe a composition containing carotene can be substantially free of vitamin A or vitamin A acid.

Murad '517 teaches a pharmaceutical composition for the treatment of acne comprising an acne reduction component. The acne reduction component is a vitamin A source, a carotenoid component, a vitamin B_6 source, and a zinc component. (Col. 3, lines 41-43; 56-58). This composition specifically includes a vitamin A source *and* a carotenoid component, indicating that Murad recognizes that these are distinct chemical components. Further, Murad '517 teaches "Vitamin A is *necessary* for healthy skin cell growth and tissue formation." (Col. 5, lines 60-61). Therefore, Murad '517 teaches away from a topical composition *substantially free of vitamin A or vitamin A acid.* At the minimum, Murand '517 fails to teach or suggest a topical composition *substantially free of vitamin A or vitamin A acid.*

Murad '163 teaches methods for treating dermatological disorders. The methods include administering a therapeutically effective amount of at least one fruit extract in an amount sufficient to neutralize free radicals; and a pharmaceutically acceptable carrier. Preferred fruit extracts include extracts from apricots, apples, peaches, pears, pineapples, papayas, pomegranates, cherries, kiwis, tangerines and oranges. The most preferred extract is extract from pomegranate. (Abstract). The dermatological agent includes at least one fruit extract from pomegranate. (Col. 6, lines 26-28). The composition may further comprise a moisturizing agent, a sunscreen or

sunblock component, antioxidants, etc. The antioxidants may be a catechin-based preparation, a vitamin A source, a ginko biloba extract, a silymarin source, a quercetin compound, a vitamin C source, a carotenoid, or a mixture thereof. (Col. 7, lines 8-11). Vitamin A is typically present in an amount from about 5 to 50 weight percent. (Col. 14, lines 57-59).

Murad '163 does not teach or suggest a composition that is similar to a composition recited in the independent claim 1, 5, 6, or 7. More importantly, Murad '163 does not teach that vitamin A or vitamin A acid should be avoided from a topical composition. Therefore, a combination of Murad '517 and Murad '163 would not produce a composition *substantially free of vitamin A or vitamin A acid.*

Gildenburg teaches personal cleansing compositions having photoprotective agents. Specifically, Gildenburg et al. taught a composition for use as a sunscreen applied during washing. The composition includes photoprotective agents of the organic type (e.g., octylmethyoxy cinnamate and oxybenzone), the inorganic type (e.g., titanium oxide and zinc oxide), or combinations of the organic and inorganic agents. (Abstract) Examiner cites Gildenburg for the teaching of surfactants. Similarly, Gildenburg fails to teach or suggest a composition should avoid vitamin A or vitamin A acid. Therefore, a combination of Murad '517, Murad '163, and Gildenburg would not produce a composition *substantially free of vitamin A or vitamin A acid.*

In view of the above, a combination of Murad (U.S. Patent No. 6,630,163), Murad (U.S. Patent No. 5,962,517), and Gildenburg et al. (U.S. Patent No. 6,217,852) fails to teach or suggest each and every limitation of the claims of the instant invention, i.e., "substantially free of vitamin A or vitamin A acid."

VIII. CONCLUSION

In view of the above, the Examiner's arguments do not support the rejection of claims 1-9 under 35 U.S.C. §103(a). Accordingly, a favorable decision from the Board is respectfully requested.

Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference 17469/004001).

Dated: May 5, 2009

Respectfully submitted,

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IX. CLAIMS APPENDIX

1. A topical composition for transdermal administration, comprising: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, and 2 - 90% w/w vitamin E, wherein the composition is substantially free of vitamin A or vitamin A acid.

2. The topical composition according to claim 1, comprising: 4 - 15% w/w vitamin C, 1 - 3% w/w vitamin B complex, 1 - 2% w/w carotene, and 20 - 65% w/w vitamin E.

3. The topical composition according to claim 1, further comprising 0.1 - 2% w/w fragrance, 1 - 5% w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water.

4. The topical composition according to claim 1, wherein the composition is for application to a local area of skin.

5. A topical composition for transdermal administration, said composition is for use in manufacturing a medication for treating acne, comedo or zit, wherein the composition comprises: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, 2 - 90% w/w vitamin E, 0.1 - 2% w/w fragrance, 1 - 5% w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water, wherein the composition is substantially free of vitamin A or vitamin A acid.

6. A topical composition for transdermal administration, said composition is for skin-care, wherein the composition comprises: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, 2 - 90% w/w vitamin E, 0.1 - 2% w/w fragrance, 1 - 5% w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water, wherein the composition is substantially free of vitamin A or vitamin A acid.

7. A topical composition for transdermal administration, said composition has an antioxidant property, wherein the composition comprises: 1 - 45% w/w vitamin C, 1 - 5% w/w vitamin B complex, 1 - 3% w/w carotene, 2 - 90% w/w vitamin E, 0.1 - 2% w/w fragrance, 1 - 5% w/w

thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water, wherein the composition is substantially free of vitamin A or vitamin A acid.

8. A method for treating acne, comedo or zit, comprising applying a topical of claim 1 to skin of a subject in need thereof.

9. The topical composition according to claim 2, further comprising 0.1 - 2% w/w fragrance, 1 - 5% w/w thickening agent, 1 - 8% w/w surfactant, and an appropriate amount of distilled water.

2. EVIDENCE APPENDIX

No evidence of the types described in 37 C.F.R. § 41.37(c)(1)(ix) has been submitted during prosecution of the present application.

3. RELATED PROCEEDINGS APPENDIX

As indicated in Section II *supra*, to the best knowledge of Appellant and the Appellant's legal representative, there are no decisions rendered by a court or the Board that may directly affect, be affected by, or have a bearing on the decision of the Board in the pending appeal.